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Platinum Team
鉑眾科技股份有限公司

MAR 2 2 2012

Pre-market Notification for EZsleep Sleep Quality Recorder

510(k) Summary of Safety and Effectiveness

1. Submitter

The Platinum Team Co., Ltd.
396 Daye Road
Beitou District
Taipei City, 11268
TAIWAN

Applicant Correspondent:
James Ho
Product Director
Phone: (011) 886 2 2896 8019
Email: jamesho@platinum-team.net

2. Name and Classification of Device

Trade Name:	EZsleep Sleep Quality Recorder
Common/Usual Name:	Heart rate recorder
Classification Name:	Electrocardiograph, Ambulatory, Without Analysis
Classification Number:	21CFR 870.2800
Product Code:	MWJ

3. Predicate Device

Trade Name	510(k) Number	Decision Date
Braemar DigiTrak Plus Holter Recorder	K993617	11/24/1999
Del Mar Lifecard CF Compact Holter Recorder	K001025	04/19/2000

4. Device Description

The EZsleep Sleep Quality Recorder is a small battery powered device designed to be simple and easy to use by a patient who suffers from sleep disorder. It is self-contained, with integrated microcontroller and LED displays and all necessary interface electronics for performing recording functions. The device has a storage function in which the recorded signals can be transmitted through a USB port to a computer for data analysis.

The proposed device is intended for adults who suffer from sleep disorders such as abnormal pauses in breathing (apnea), or instances of abnormally low breathing during sleep (hypopnea). This device is not intended to substitute for a hospital device for diagnosis of sleep disorders. This device is also not intended for recording and transmission of user's heart rate signal simultaneously. Users with implanted pacemaker are not recommended to use this device.

5. Indications for Use

The EZsleep Sleep Quality Recorder is to be placed on patient's chest for recording of heart rate signals while patient is asleep. The recorded data is for sleep quality analysis using the software, ***Sleep Quality*** Apnea Examination System, which was already cleared by US FDA, as K070855.

The EZsleep Sleep Quality Recorder is not intended for monitoring purpose.

6. Technological Characteristics

The technological characteristics of the EZsleep Sleep Quality Recorder are as follows:
- Powered by a lithium battery;
- Operating voltage and current: 3.8 – 4.2 v, 1.7 – 2.4 mA;
- The battery can be recharged in less than 4 hours;
- The device does not allow recording while recharging is in progress;
- Simple and easy to use
- Self-contained, with integrated microcontroller and LED displays and all necessary interface electronics for performing recording functions.
- Has a storage function for up to four 8-hour recording;
- Recorded signals can be transmitted through a USB port to a computer for data analysis.

7. Performance Summary

Various bench tests were performed to ensure that the EZsleep Sleep Quality Recorder meets all functional and performance for its intended use. The electrical safety and EMC requirements were tested by independent labs in accordance with the requirements specified in IEC 60601-1 and IEC 60601-1-2. Biocompatibility of the recorder outer casing material was tested according to ISO 10993 guidelines for "short-term exposure, skin contact devices".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 2 2 2012

The Platinum Team Co., Ltd.
c/o Mr. James Ho
Product Director
396 Daye Road
Beitou District
Taipei City, 11268
TAIWAN

Re: K112573
Trade/Device Name: EZsleep Sleep Quality Recorder
Regulatory Number: 21 CFR 870.2800
Regulation Name: Ambulatory Electrocardiograph
Regulatory Class: II (two)
Product Code: MWJ
Dated: March 1, 2012
Received: March 2, 2012

Dear Mr. Ho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112573

Platinum Team
鉑眾科技股份有限公司

Indication for Use

510(k) Number (if known):

Device Name:
EZsleep Sleep Quality Recorder

Indications For Use:
The EZsleep Sleep Quality Recorder is to be placed on patient's chest for recording of heart rate signals while patient is asleep. The recorded data is for sleep quality analysis.

The EZsleep Sleep Quality Recorder is not intended for monitoring purpose.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112573